AUG 3 1 2001

K012162

510(k) Summary of Safety and Effectiveness for the Basic Fragment Set

Proprietary Name:	Stryker Plating System Basic Fragment Set
Common Name:	Bone Plate System
Classification Name and Reference	21 CFR §888.3030 and 21 CFR §888.3040
Regulatory Class:	Class II
For Information contact:	Karen Ariemma, Regulatory Affairs Specialist
	Howmedica Osteonics Corp.
	59 Route 17
	Allendale, NJ 07401-1677
	Phone: (201) 760-8187
	Fax: (201) 760-8435
Date Summary Prepared:	July 10, 2001

Intended Use:

The Basic Fragment Set is intended for use in long bone fracture fixation.

Description:

The Basic Fragment Set is part of the Stryker Plating System. The Basic Fragment Set is consists of plates and screws for the fixation of fractures of the cortical and metaphyseal area of long bones as well as fractures of the pelvis. The implant set is available either in stainless steel (316L) or titanium alloy (Ti6Al4V).

Substantial Equivalence:

Equivalency of this device is based on similarities in intended use, materials, and design to other currently marketed plating systems. Analysis has been conducted demonstrating substantial equivalence to a currently marked device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 1 2001

Ms. Karen Ariemma
Regulatory Affairs Specialist
Howmedica Osteonics Corportion
59 Route 17
Allendale, New Jersey 07401-1677

Re: K012162
Trade Name: Basic Fragment Set
Regulation Number: 888.3030
Regulatory Class: II
Product Codes: HRS, HWC
Dated: July 10, 2001
Received: July 11, 2001

Dear Ms. Ariemma:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Devices Evaluation
Center for Devices and
Radiological Devices

Enclosure

510(k) Number (if known): K012162

Device Name: Basic Fragment Set

The Basic Fragment Set is intended for use in long bone fracture fixation.

Reconstruction plates, wide and narrow straight and waisted compression-plates are indicated for fixation of long bone fractures including but not limited to:

- Fractures of the femur
- Fractures of the tibia
- Fractures of the humerus
- Fractures of the pelvis

T-Plates, T-buttress Plates and L-buttress-Plates are indicated for fractures at the proximal or distal end of long bones including but not limited to:

- Fractures of the femoral condyles
- Fractures of the tibial plateau
- Fractures of the distal tibia
- Fractures of the proximal-humerus

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K012162

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use____ OR Over-The-Counter Use____

(Per 21 CFR 801.109) (Optional Format 1-2-96)